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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/766,610 | 01/27/2004 | Gregory J. LaRosa | 1855.1052-029 | 3808 |
| 26161 | 7590 | 03/13/2007 | EXAMINER | |
| FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | BOESEN, AGNIESZKA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 03/13/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|------------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/766,610 | LAROSA ET AL. |
| | Examiner | Art Unit |
| | Agnieszka Boesen | 1648 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on December 18, 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-5,7-13,15,16,18-22 and 66-85 is/are pending in the application.
 - 4a) Of the above claim(s) 4,8,10 and 12 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 3, 5, 7, 9, 11, 13, 15, 16, 18, 19-22, and 66-85 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed December 18, 2006 in response to the Office Action of June 22, 2006 is acknowledged and has been entered. Claims 2, 6, 14, 17 and 23-65 have been canceled. Claims 1, 3-5, 7-13, 15, 16, 18, 19, and 22 have been amended. Claims 66-85 have been added. Claims 1, 3, 5, 7, 9, 11, 13, 15, 16, 18, 19-22, and 66-85 are under examination in the present Office action.

Restriction/Election

Claims 4, 8, 10, and 12 are withdrawn because the claims are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The elected and examined invention is:

I. Claims 1-19, and 22 drawn to an isolated nucleic acid, expression vector, and a fused gene encoding a humanized immunoglobulin light chain, classified in class 536, subclass 23.53. The examined sequences are: an amino acid sequence of a variable light chain region of SEQ ID NO: 9, and its encoding nucleic acid of SEQ ID NO: 95, and a variable heavy chain region of SEQ ID NO: 10 and its encoding nucleic acid of SEQ ID NO: 96.

The newly submitted claims are drawn to:

II. Claims 39, 41, and 65, drawn a humanized immunoglobulin light chain, classified in class 530, subclass 387.1.

The species are: SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 98, or SEQ ID NO: 107.

III. Claims 40, and 42, drawn to a humanized immunoglobulin heavy chain, classified in class 530, subclass 387.1.

The species are: SEQ ID NO: 17, SEQ ID NO: 18 SEQ ID NO: 19, SEQ ID NO: 20, or SEQ ID NO: 97.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. The invention of the above group I has been examined in the action on the merits of June 22, 2006. Because claims 4, 8, 10, and 12 have been amended to recite the non-elected invention, such as sequences encoding a humanized light chain and a humanized heavy chain, the claims are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Regarding claims 3, 7, 9, 11, the claims have been amended to cancel the originally elected invention, such as amino acid sequences SEQ ID NO: 9 and 10 comprising the fragment of a light and heavy chain **variable** regions of the antibody, to recite new sequences, for the light chain variable region SEQ ID NO: 12, 13, 14, 15, and 107, and for the heavy variable region SEQ ID NO: 17, 18, 19, and 20. The specification (see page 31 and 32) defines SEQ ID NO: 12, 13, 14, 15, and 107 as sequences representing **constant** light chain regions of human origin, and SEQ ID NO: 17, 18, 19, or 20 representing **constant** heavy chain regions of human origin. The claims are currently rejected under 35 U.S.C. 112, first paragraph for new matter (see below), because the specification does not describe SEQ ID NO: 12, 13, 14, 15, or 107 and SEQ ID NO:

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17, 18, 19, or 20 as representing variable regions as claimed in claims 3, 7, 9, 11. If Applicant amends claims 3, 7, 9, 11 to cancel the recitation of "variable regions" a restriction requirement will be issued to elect one sequence for prosecution on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of claims 9, 11, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of Applicants amendment to the claims.

Rejection of claims 2, 6, 13, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of Applicants arguments.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 2 and 6 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is moot** because Applicant canceled the claims.

Rejection of claims 2 and 14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is moot** because Applicant canceled the claims.

Rejection of claims 10 and 12 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is moot** because the claims are withdrawn.

Rejection of claims 11 and 13 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in view of Applicants arguments.

Rejection of claim 14 under 35 U.S.C. 112, first paragraph, is **moot** because Applicant canceled the claim.

Rejection of claims 13 and 15 under 35 U.S.C. 112, first paragraph, is **withdrawn** in view of Applicant's amendment.

Rejection of claims 15, 18, and 19 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell, wherein the cell is isolated, purified or cultured, does not reasonably provide enablement for a host cell comprised within a living organism such as a transgenic animal or human is **withdrawn** in view of Applicant's amendment.

New Rejections necessitated by Applicant's amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, 7, 9, 11, 13, 15, 16, 18, 19-22, and 66-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 7, 9, 11 have been amended to cancel amino acid sequences SEQ ID NO: 9 and 10 comprising the fragments of a light and heavy chain **variable** regions of the antibody, to recite new sequences: for the light chain variable region SEQ ID NO: 12, 13, 14, 15, or 107; and

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for the heavy variable region SEQ ID NO: 17, 18, 19, or 20. The specification (see page 31 and 32) defines SEQ ID NO: 12, 13, 14, 15, or 107 as sequences representing **constant light chain** regions of human origin, and SEQ ID NO: 17, 18, 19, or 20 representing **constant heavy chain** regions of human origin. The specification does not describe SEQ ID NO: 12, 13, 14, 15, 107 or SEQ ID NO: 17, 18, 19, and 20 as representing variable regions of an antibody as claimed in claims 3, 7, 9, 11. It is unclear how the newly recited sequences are variable regions.

Clarification and correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 7, 9, 11, 13, 15, 16, 18, 19-22, and 66-85 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 3, 7, 9, 11, the claims have been amended to cancel the amino acid sequences SEQ ID NO: 9 and 10 comprising the fragment of a **light and heavy chain variable** regions of the antibody, to recite new sequences: for the light chain variable region SEQ ID NO: 12, 13, 14, 15, or 107, and for the heavy variable region SEQ ID NO: 17, 18, 19, or 20. The specification (see page 31 and 32) defines SEQ ID NO: 12, 13, 14, 15, or 107 as sequences representing **constant light chain** regions of human origin, and SEQ ID NO: 17, 18, 19, or 20 representing

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constant heavy chain regions of human origin. The claims are rejected because the specification does not describe SEQ ID NO: 12, 13, 14, 15, 107 or SEQ ID NO: 17, 18, 19, and 20 as representing variable regions as claimed in claims 3, 7, 9, 11. Thus the variable regions comprising SEQ ID NO: 12, 13, 14, 15, or 107 and SEQ ID NO: 17, 18, 19, or 20 are considered to be new matter.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground of rejections presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB
Agnieszka Boesen, Ph.D.

3/9/2007

Stacy B. Chen 3/9/07
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PRIMARY EXAMINER